

Message

---

**From:** Cyran, Carissa [Cyran.Carissa@epa.gov]  
**Sent:** 8/17/2021 9:43:49 PM  
**To:** Perron, Monique [Perron.Monique@epa.gov]; Friedman, Dana [Friedman.Dana@epa.gov]; Wilbur, Donald [Wilbur.Donald@epa.gov]  
**CC:** Vogel, Dana [Vogel.Dana@epa.gov]; Lowit, Anna [Lowit.Anna@epa.gov]; Pyne, Jaclyn [Pyne.Jaclyn@epa.gov]; Feitel, Alexandra [feitel.alexandra@epa.gov]; Kiely, Timothy [Kiely.Timothy@epa.gov]; Reaves, Elissa [Reaves.Elissa@epa.gov]; Biggio, Patricia [biggio.patricia@epa.gov]  
**Subject:** Re: need more on SAP....  
  
**Flag:** Follow up

Thank you, Monique. This is great and should address what OCSPP IO is looking for. I am going to send this information forward for questions 2 and 4. I will also send the epi language forward. Again, thank you for the quick turnaround on this!

---

**From:** Perron, Monique <Perron.Monique@epa.gov>  
**Sent:** Tuesday, August 17, 2021 5:34 PM  
**To:** Cyran, Carissa <Cyran.Carissa@epa.gov>; Friedman, Dana <Friedman.Dana@epa.gov>; Wilbur, Donald <Wilbur.Donald@epa.gov>  
**Cc:** Vogel, Dana <Vogel.Dana@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>; Pyne, Jaclyn <Pyne.Jaclyn@epa.gov>; Feitel, Alexandra <feitel.alexandra@epa.gov>; Kiely, Timothy <Kiely.Timothy@epa.gov>; Reaves, Elissa <Reaves.Elissa@epa.gov>; Biggio, Patricia <biggio.patricia@epa.gov>  
**Subject:** RE: need more on SAP....

Hi Carissa,

Since the updated lit review actually focuses on providing support for the OPs other than chlorpyrifos and refers to earlier reviews for chlorpyrifos, I think it might be easier to point them to the 2014 risk assessments for the neurodevelopment discussion, as well as some discussion of cholinesterase inhibition and the PBPK model. The 2011 RA has an appendix of studies with cholinesterase measurements.

Thanks,  
Monique

2014 RA: <https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0195>

Acetylcholinesterase inhibition in laboratory animals – Section 4.4.1  
Neurodevelopmental outcomes in laboratory animals - Section 4.4.2  
Epi studies – Section 4.5  
Weight of evidence evaluation of neurodevelopmental outcomes – Section 4.6  
PBPK model information – Section 4.8

2011 RA: <https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0025>

Summary table of studies – appendix A

~~~~~  
Monique Perron  
U.S. Environmental Protection Agency  
Office of Pesticide Programs | Health Effects Division  
Senior Science Advisor  
*Email:* [perron.monique@epa.gov](mailto:perron.monique@epa.gov)  
*Phone:* (703) 347-0395

\*\*\*\*\*

Confidentiality Notice: This e-mail message, including any attachments, is for the sole use of the intended recipient(s) and may contain confidential, deliberative, internal, and/or privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply e-mail and destroy all copies of the original message.

---

**From:** Cyran, Carissa <Cyran.Carissa@epa.gov>

**Sent:** Tuesday, August 17, 2021 4:44 PM

**To:** Friedman, Dana <Friedman.Dana@epa.gov>; Wilbur, Donald <Wilbur.Donald@epa.gov>; Perron, Monique <Perron.Monique@epa.gov>

**Cc:** Vogel, Dana <Vogel.Dana@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>; Pyne, Jaclyn <Pyne.Jaclyn@epa.gov>; Feitel, Alexandra <feitel.alexandra@epa.gov>; Kiely, Timothy <Kiely.Timothy@epa.gov>; Reaves, Elissa <Reaves.Elissa@epa.gov>; Biggio, Patricia <biggio.patricia@epa.gov>

**Subject:** Re: need more on SAP....

Thank you, Dana. Michal is requesting a list of studies for the two questions below, however, if we can't provide the list, can cite the exact pages or chapters to the linked documents in questions 2 and 3.

### **List of studies that show neurodevelopmental effects and brief description**

The studies demonstrating evidence of neurodevelopmental effects are summarized and discussed in EPA's document entitled '*Updated Literature Review on Neurodevelopmental Effects & FQPA Safety Factor Determination for the Organophosphate Pesticides*', which can be found at <https://www.regulations.gov/document/EPA-HQ-OPP-2010-0119-0060> - For this document, is section 2.1 the correct section, although the title is for OPs other than chlorpyrifos?

### **List of key studies related to enzyme inhibition and acetylcholinesterase (sp)**

The database for chlorpyrifos comprises numerous studies evaluating inhibition of the enzyme acetylcholinesterase, which is a well-established mode of action (MOA) for organophosphate compounds that leads to overstimulation of the nervous system. Studies in laboratory animals spans multiple routes of exposure, animal species, lifestages, and durations. The animal studies have been summarized in numerous chlorpyrifos risk assessments, including the 2011 Preliminary Human Health Risk Assessment drafted for Registration Review (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0025>). Additionally, acetylcholinesterase inhibition data have been generated for the development of the chlorpyrifos physiologically-based, pharmacokinetic-pharmacodynamic (PBPK-PD) model, which has been utilized in recent chlorpyrifos risk assessments for Registration Review (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0195>). These documents provide critical studies that have been as the basis for the Agency's risk assessments.

---

**From:** Friedman, Dana <Friedman.Dana@epa.gov>

**Sent:** Tuesday, August 17, 2021 3:56 PM

**To:** Wilbur, Donald <Wilbur.Donald@epa.gov>; Perron, Monique <Perron.Monique@epa.gov>

**Cc:** Vogel, Dana <Vogel.Dana@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>; Pyne, Jaclyn <Pyne.Jaclyn@epa.gov>; Feitel, Alexandra <feitel.alexandra@epa.gov>; Kiely, Timothy <Kiely.Timothy@epa.gov>; Reaves, Elissa <Reaves.Elissa@epa.gov>; Biggio, Patricia <biggio.patricia@epa.gov>; Cyran, Carissa <Cyran.Carissa@epa.gov>

**Subject:** need more on SAP....

OCSPP wants more on the SAP, asking: "How is the SAP thing unclear? Aren't there quotes we can pull out on the epi data?"

Are you ok with this pulled from the rule:

# **Ex. 5 Deliberative Process (DP)**

Dana L. Friedman  
Chief, Risk Management and Implementation Branch 1  
Pesticide Re-Evaluation Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
703-347-8827